IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CHRISTINE WILTGEN and MARK S. WILTGEN,	)	
Plaintiffs,	)	
	)	No. 12-cv-2400
v.	)	
	)	Hon. Amy J. St. Eve
ETHICON, INC. and JOHNSON JOHNSON,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Court Judge:

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants") have moved pursuant to the Federal Rules of Evidence and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), to exclude certain opinions of Plaintiffs Christine Wiltgen and Mark S. Wiltgen's (collectively, "Plaintiffs") expert, Dr. Daniel Elliott, M.D. (R. 175.) Defendants contend that they are addressing challenges they made before the Southern District of West Virginia (the "MDL Court")—which handled extensive discovery and pre-trial issues as part of a multidistrict litigation before remanding this case to the Court for trial—that the MDL Court reserved for trial.[1] (R. 176.) For the following reasons, the Court grants in part and denies in part Defendants' motion.

[1] As the Court noted in its June 9, 2017 Order for the *Walker v. Ethicon, Inc.* case, the MDL Court's ruling that certain issues were "reserved for trial" does not strip the Court of its authority to decide properly raised issues before trial. (*Walker* Docket, No. 12-cv-1801, Dkt. No. 156.)

BACKGROUND

The Court assumes the parties' familiarity with this case and with the MDL Court's prior rulings. The Court will address specific facts to the extent they are relevant below.

On July 14, 2006, at Good Samaritan Hospital in Downers Grove, Illinois, Dr. Denise Elser, M.D., implanted Defendants' Gynecare TVT Device (the "TVT" or the "TVT device/product") in Plaintiff to treat her stress urinary incontinence ("SUI"). (R. 1 at ¶ 20, 24.) Plaintiffs filed this case in 2012 alleging that the TVT product caused significant injury to Plaintiff Mrs. Wiltgen and her husband. (*Id*. at ¶ 40, 77.)

After extensive briefing on Defendants' motion for summary judgment (MDL Court Docket, No. 12-cv-1216, Dkt. Nos. 79-81, 89-90, 91, 93-95) and Defendants' alternative motion for partial summary judgment (*Id*., Dkt. Nos. 100-101, 107-108, 110), the MDL Court granted in part and denied in part the partial summary judgment motion. (*Id*., Dkt. No. 141.) Plaintiffs conceded a number of claims (strict liability – manufacturing defect, constructive fraud, violation of consumer protection laws) and the MDL Court granted Defendants' summary judgment as to some of Plaintiffs' remaining claims (strict liability – defective product, breach of implied warranty – fitness for a particular purpose). (*Id*.) Accordingly, Plaintiffs currently have claims for negligence, strict liability – design defect, strict liability – failure to warn, fraudulent concealment, breach of express warranty, loss of consortium, and punitive damages. (R. 1; MDL Court Docket, Dkt. No. 141.)

The current *Daubert* motion concerns Dr. Elliott, who is board-certified in urology, and obstetrics and gynecology. (R. 176-3, Elliott Report, 1.) Dr. Elliott is a pelvic surgeon and urogynecologist who Plaintiffs designated as an expert to give general expert opinions regarding the TVT device that Plaintiff Mrs. Wiltgen had surgically implanted to treat her SUI. Dr. Elliott

specializes "in treating pelvic organ prolapse and urinary incontinence in women." (*Id.*) As previously noted, the MDL Court issued a number of rulings regarding Defendants' challenges to Dr. Elliott's testimony. (MDL Court Docket, Dkt. No. 131.) The MDL Court, however, reserved certain issues for this Court. After the MDL Court remanded this case to the Northern District of Illinois, the Court instructed the parties to file motions on any outstanding *Daubert* issues and Defendants filed the current motion.

LEGAL STANDARD

"A district court's decision to exclude expert testimony is governed by Federal Rules of Evidence 702 and 703, as construed by the Supreme Court in [*Daubert*]." *Brown v. Burlington N. Santa Fe Ry. Co.*, 765 F.3d 765, 771 (7th Cir. 2014). "The rubric for evaluating the admissibility of expert evidence considers whether the expert [is] qualified, whether his methodology [is] scientifically reliable, and whether the testimony would . . . assist[] the trier of fact in understanding the evidence or in determining the fact in issue." *Hartman v. EBSCO Indus., Inc.*, 758 F.3d 810, 817 (7th Cir. 2014); *see also Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 704 (7th Cir. 2015) ("Rule 702 and *Daubert* require the district court to determine whether proposed expert testimony is both relevant and reliable."). Although the Seventh Circuit reviews "the district court's application of *Daubert* . . . de novo," if "the court adhered to the *Daubert* framework, then its decision on admissibility is reviewed for abuse of discretion." *Estate of Stuller v. United States*, 811 F.3d 890, 895 (7th Cir. 2016).

A district court's evaluation of expert testimony under *Daubert* does not "take the place of the jury to decide ultimate issues of credibility and accuracy." *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 805 (7th Cir. 2012); *see also Ortiz v. City of Chicago*, 656 F.3d 523, 536 (7th Cir. 2011) ("The admissibility determination is not intended to supplant the adversarial process, and so even

'shaky' testimony may be admissible."). Once it is determined that "the proposed expert testimony meets the *Daubert* threshold of relevance and reliability, the accuracy of the actual evidence is to be tested before the jury with the familiar tools of 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *Lapsley*, 689 F.3d at 805 (quoting *Daubert*, 509 U.S. at 596); *see also Manpower, Inc. v. Ins. Co. of Pennsylvania*, 732 F.3d 796, 806 (7th Cir. 2013) ("The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact, or, where appropriate, on summary judgment." (quoting *Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000))).

A district court's inquiry under *Daubert* is a flexible one and district courts have wide latitude in performing their gate-keeping function under the Federal Rules of Evidence. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); *Hartman*, 758 F.3d at 818. "[T]he key to the gate is not the ultimate correctness of the expert's conclusions," rather, "it is the soundness and care with which the expert arrived at her opinion[.]" *C.W. ex rel. Wood v. Textron, Inc.*, 807 F.3d 827, 834 (7th Cir. 2015) (second alteration in original) (quoting *Schultz v. Akzo Nobel Paints, LLC*, 721 F.3d 426, 431 (7th Cir. 2013)). The "proponent of the expert bears the burden of demonstrating that the expert's testimony would satisfy the *Daubert* standard" by a preponderance of the evidence. *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 705 (7th Cir. 2009); *see also United States v. Saunders*, 826 F.3d 363, 368 (7th Cir. 2016) ("[F]or expert testimony to be admissible, the proponent of the evidence must establish that the expert's testimony is reliable (and relevant) by a preponderance of the evidence.").

ANALYSIS

Defendants move to exclude Dr. Elliott's opinions on (1) non-synthetic mesh procedures and other synthetic mesh devices as safer alternatives to the TVT; (2) the adequacy of Ethicon's research and testing; (3) other risks and complications of the TVT; and (4) the adequacy of Ethicon's product warnings. For the following reasons, the Court grants in part and denies in part Defendants' motion to exclude Dr. Elliott's testimony.

I. Dr. Daniel Elliott

Dr. Elliott is an associate professor of urology in the section of Female Urology and Reconstructive Surgery at the Mayo Clinic Graduate School of Medicine in Rochester, Minnesota. (Elliott Report, 1.) He is certified by the Board of Urology and the Board of Obstetrics and Gynecology in female pelvic medicine and reconstructive surgery. (*Id.*) For 15 years, he has specialized "in treating pelvic organ prolapse and urinary incontinence in women." (*Id.*) Dr. Elliott has delivered numerous lectures on the evaluation, treatment and surgical options, and management of complications related to pelvic organ prolapse and SUI in women. (*Id.*) He is an editor and/or reviewer for 15 urologic and/or gynecologic journals, and has kept abreast of current medical literature on SUI treatment options. (*Id.* at 3-4.) In developing his opinions, Dr. Elliott has also reviewed internal Ethicon documents and depositions of its personnel. (*Id.* at 4.)

Dr. Elliott is of the opinion that mesh that is lighter-weight, has smaller pores, and is cut mechanically would perform better than the TVT device as designed. (*Id.* at 13-34.) He also maintains that non-synthetic mesh procedures and other synthetic mesh devices are safer alternatives to the TVT. (*Id.* at 5-13.) Specifically, Dr. Elliott thinks highly of the Burch

colposuspension procedure[2] and pubovaginal slings, and believes they are better treatment alternatives over devices like the TVT. (*Id*. at 8.) Dr. Elliott also "believe[s] that all the currently available mesh slings…on the market as of right now and their technique[s] are unsafe" (R. 176-4, Elliott 9/26/15 Dep., 145:16-18.) and that "[m]esh should not be placed in the vagina" (*Id*. at 285:22.).

In addition, Dr. Elliott questions the adequacy of Ethicon's research and testing, and the TVT's product warnings. According to Dr. Elliott, Ethicon failed to: disclose and/or downplayed the adverse risks, complications, and product information in its Instructions for Use ("IFU") (*Id*. at 34-37.); conduct appropriate studies related to the TVT (*Id*. 37-38.); and consider numerous known risks and hazards of the TVT in its design process (*Id*. at 38-39.).

II. Testimony Regarding Non-Synthetic Mesh Procedures as Safer Alternative

Defendants argue that the Court should preclude Dr. Elliott from testifying that non-synthetic mesh procedures are a safer alternative for the surgical treatment of SUI. (R. 176 at 2-4.) Defendants claim that the alternatives Dr. Elliott discusses, such as the Burch colposuspension procedure, native tissue pubovaginal slings, and other forms of native tissue non-mesh surgical repair, are not medical devices, and that therefore his opinion is irrelevant and prejudicial. (*Id*.)

In response, Plaintiffs argue that the evidence is directly relevant to the risk-utility test used to determine if a product is "unreasonably dangerous" under Illinois law. (R. 189 at 2-8.) While West Virginia law may require proof of a safer alternative design, Plaintiffs may prevail in Illinois on their defective design claim by showing that the risks of the product outweighed its

[2] Burch colposuspension procedure is another SUI treatment option. The paravaginal fascia is attached to the Cooper's ligaments with the goal of suspending and stabilizing the urethra. (*See, e.g*., Elliott Report, 8; R. 189-2, Bales Report, 4; R. 189-3, Rosenzweig Report, 7-9.)

benefits—and alternatives, whether products or not, are helpful in making the risk-utility calculation. (*Id*. at 3-5) Additionally, Plaintiffs argue that this evidence is relevant to their negligence claim under Illinois law because it may help the jury determine whether Ethicon acted as a reasonably prudent manufacturer. (*Id*. at 5-6.)

Further, Plaintiffs argue that Defendants are likely to open the door to this evidence since Ethicon's experts and witnesses have asserted that the TVT product is the "best option" or the "gold standard" for the treatment of SUI. (*Id*. at 6-7.) In the alternative, Plaintiffs argue that at the very least, the Court should allow testimony regarding native tissue pubovaginal slings, which are assuredly categorized as products and include other materials in addition to native tissue. (*Id*. at 7-8.) The jury should decide whether a product made primarily from native tissue is a safer alternative to TVT, according to Plaintiffs. (*Id*.)

The Court agrees with Defendants that evidence regarding a different surgical procedure not involving mesh is irrelevant to the existence of a safe alternative design for the product at issue in this case. *See Schmidt v. C.R. Bard, Inc.*, 2013 WL 3802804, *2 (D. Nev. July 22, 2013) ("Neither is the Court swayed by Plaintiff's argument that the testimony of Dr. Petersen to the effect that Plaintiff's hernia repair could have been accomplished without use of the 3DMax Mesh. The fact that an alternative method of surgical hernia repair was potentially available does not support Plaintiff['s] design defect claim. As argued by Defendants, non-mesh repair is not an alternative design and does not meet Plaintiff's burden to support this particular claim."); *see also, e.g.*, *Theriot v. Danek Med., Inc.*, 168 F.3d 253, 255 (5th Cir. 1999); *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999); *Linsley v. C.R. Bard*, 2000 WL 343358, *3 (E.D. La. Mar. 30, 2000) (explaining that while there were "'alternative techniques' for repairing a ventral hernia using Marlex Mesh," the plaintiff failed to show that there was an alternative safer

design); *Niedner v. Ortho-McNeil Pharm., Inc.*, 58 N.E.3d 1080, 1086–87 (Mass. App. Ct. 2016) ("While both products are hormonal contraceptives that prevent pregnancy, the difference in the drug delivery method, each of which has its own advantages and disadvantages, makes the pill fundamentally different from the patch. As such, one cannot serve as a safer alternative for the other." (citations omitted)).

Plaintiffs are correct, however, in arguing that this evidence is nonetheless relevant to determine if a product is unreasonably dangerous. Under Illinois law, a plaintiff may prove that a product design is unreasonably dangerous using the risk-utility test. *See Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 346–53 (Ill. 2008), *opinion modified on denial of reh'g* (Dec. 18, 2008) (balancing of risks and benefits is one way to prove that a product was unreasonably dangerous in a strict product liability design defect case); *Calles v. Scripto-Tokai Corp*., 864 N.E.2d 249, 260–61 (Ill. 2007) (listing 7 non-exhaustive factors of risk-utility analysis). The Illinois Supreme Court has set forth the following non-exhaustive factors when applying this test:

> (1) The usefulness and desirability of the product—its utility to the user and to the public as a whole.
> (2) The safety aspects of the product—the likelihood that it will cause injury, and the probable seriousness of the injury.
> (3) The availability of a substitute product which would meet the same need and not be as unsafe.
> (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility.
> (5) The user's ability to avoid danger by the exercise of care in the use of the product.
> (6) The user's anticipated awareness of the dangers inherent in the product and their availability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions.
> (7) The feasibility, on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance.

Calles, 864 N.E.2d at 260–61 (citing J. Wade, *On The Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 837–38 (1973)). The availability of other safe and effective procedures (including surgical procedures) to treat the same condition is relevant and admissible to show the utility of a product. *See also Herrera-Nevarez by Springer v. Ethicon, Inc*., 2017 WL 3381718, *7 (N.D. Ill. Aug. 6, 2017) (admitting Dr. Elliott's testimony on the same issue for the same reason in a vaginal mesh product case).

Plaintiffs have not met their burden of establishing that Dr. Elliott's opinion is relevant to their negligence claim under Illinois law. Industry practices and standards help inform a jury about what constitute a reasonably prudent manufacturer. Plaintiffs only give one sentence of explanation of how this testimony is related to the negligence claim and they cite no binding case law to bolster this connection.

This evidence is also relevant, however, to rebut Defendants' claims that the TVT and similar products are the "gold standard" for treating SUI.[3]

The Court denies Defendants' motion with regard to Dr. Elliott's testimony that non-synthetic mesh procedures are a safer alternative for the surgical treatment of SUI. This evidence is allowed in for risk-utility analysis and as rebuttal testimony.

III. Testimony Regarding Other Synthetic Mesh Devices as Safer Alternative

Defendants argue that because "Dr. Elliott has testified that he believes that all transvaginal mesh is 'unsafe' and that '[m]esh should not be placed in the vagina' in any form or fashion," Dr. Elliott cannot testify that other synthetic mesh devices are safer than TVT. (R. 176 at 4 (quoting Dr. Elliott 9/26/2015 Dep.).) Although the MDL Court has already ruled to allow Dr. Elliott to testify about the alleged benefits of mesh that is lighter-weight and has larger pores,

[3] Plaintiffs' alternative argument is moot since the Court is allowing in broader evidence. There is no need to limit the testimony to native tissue pubovaginal slings.

and in general found him "qualified to testify about whether one mesh is safer than another" (MDL Court Docket, Dkt. No. 131 at 9; R. 176-2 at 10.), Defendants argue that this Court should exclude his testimony on this issue. (R. 176 at 4-5.)

Plaintiffs admit that "Dr. Elliott is not an advocate for any synthetic mesh." (R. 189 at 8.) Plaintiffs argue, however, that despite the fact that Dr. Elliott believes all synthetic products are inferior, the Court should allow him to explain the superiority of other synthetic products over the TVT. (*Id*. at 8-10.) In addition, the MDL Court "has already found that Dr. Elliott is competent to testify about the benefits of other lighter weight/larger p[o]re mesh" and urge the Court to deny Defendants' motion. (*Id*. at 10.)

The Court follows the prior ruling of the MDL Court. Specifically, the Court denies Defendants' motion and will permit Dr. Elliott to testify regarding other synthetic mesh devices. Dr. Elliott is clearly qualified to opine on different types of vaginal mesh products after years of specializing in SUI and his other professional experiences, even though he himself does not recommend vaginal mesh. The fact that Dr. Elliott evidently does not believe that any such devices are safe does not preclude him from comparing or ranking such products. *See Herrera-Nevarez*, 2017 WL 3381718 at *7. As Judge Kennelly pointed out when also admitting Dr. Elliott's evidence on this point in *Herrera-Nevarez*, Defendants' argument goes to the weight of the evidence, to be decided by the jury—not to its admissibility. *Id*.

IV. Testimony Regarding the Adequacy of Ethicon's Research and Testing

Defendants urge the Court to exclude Dr. Elliott's testimony about Ethicon's research and testing because it goes beyond his competency and qualifications. (R. 176 at 5-7.) Defendants invoke an MDL Court ruling in which Judge Goodwin stated that he "doubted the relevance of testimony on the adequacy of Ethicon's clinical testing and research….[as] such

matters seem to say very little about the state of the product itself (i.e., whether or not it was defective) when it went on the market." (*Id*. (quoting MDL Court Docket, Dkt. No. 131, 12; R. 176-2 at 13).)

According to Defendants, nothing in Dr. Elliott's background makes him knowledgeable or experienced "to testify about the standard of care for a manufacturer." (R. 176 at 5-6.) Dr. Elliott "has never been involved in the manufacture and launch of a drug or medical device." (*Id*. at 6.) Defendants point out that Dr. Elliott "is unable to identify a single rule or regulation that would require Defendants to conduct different testing. (*Id*.) "Dr. Elliott can only speculate about what those results [of the "additional testing and studies"] would have shown" and his opinion "is based purely on unscientific[,] personal, subjective belief." (*Id*.) Defendants draw parallels between Dr. Elliot in this case and Dr. Bruce Rosenzweig, an expert who Judge Goodwin excluded from testifying about a similar issue. (*Id*. at 7.)

Plaintiffs argue that Dr. Elliott's opinions on Ethicon's research and testing relate to his knowledge and expertise. (R. 189 at 11-12.) According to Plaintiffs, Defendants misunderstand Plaintiffs' purpose—Plaintiffs never intended Dr. Elliott to opine on the regulatory or legal adequacy of the testing, only about "the state of the clinical testing and data on the TVT…as well as the factual underpinnings of whether or not testing was conducted." (*Id*. at 11 (emphasis removed).) Plaintiffs point to Dr. Elliott's experience in the field, including as an editor and/or reviewer of 15 urologic and/or gynecologic journals, his extensive publications, and his work as an investigator for seven industry-sponsored studies. (*Id*.) "Dr. Elliott only intends to explain how Ethicon's lack of testing, in certain areas, has impacted his opinions." (*Id*. (emphasis removed).) Plaintiffs will not ask Dr. Elliott to opine on the regulatory or legal adequacy of the testing.

The Court agrees with Defendants that Dr. Elliott lacks the necessary background to opine on the regulatory or legal adequacy of Ethicon's testing. He does not have experience in medical device manufacturing or knowledge of the accompanying regulatory scheme, thus he does not have the foundation to render such opinions. Accordingly, the Court grants this aspect of Defendants' motion.

The Court further finds that Dr. Elliott cannot opine on whether Ethicon appropriately responded to alleged safety issues with more testing and research. Dr. Elliott does not have the necessary knowledge or experience to give his opinion on how a medical device manufacturer should react to such potential problems. This testimony relates to Dr. Elliott's opinion on the Food and Drug Administration's adverse event reporting—testimony which the MDL Court has already excluded. (R. 176-2 at 11.) Plaintiffs argue that Dr. Elliott would merely give his opinion on the "factual underpinnings of whether or not testing was conducted." (R. 189 at 11.) Such an opinion, however, would be nothing more than a summary of corporate documents from an expert witness, which the MDL Court rejected. (MDL Court Docket, Dkt. No. 131 at 13-14; R. 176-2 at 14-15 (the MDL Court advised Plaintiffs not to have an expert witness serve as "a conduit for corporate information").) The Court grants Defendants' motion in this regard as well.

Dr. Elliott may testify, however, regarding what impact the studies had on his opinions in this case. As Judge Kennelly held in the *Herrera-Nevarez* case, as a clinician Dr. Elliott should be able to testify "whether and why…studies and testing conducted by [D]efendants or others are sufficient to impact his opinions regarding the TVT-O[4] or similar devices." 2017 WL 3381718 at *7.

[4] The TVT-O device is a different product than the TVT device at issue in this case.

The Court grants in part and denies in part Defendants' motion to exclude Dr. Elliott's testimony regarding the adequacy of Ethicon's research and testing. Dr. Elliott is not allowed to give testimony about regulatory or legal adequacy, or to comment about the absence of studies in response to negative feedback. Dr. Elliott can, however, explain how the studies and tests impacted his opinions in this case.

V. Testimony Regarding Other Complications Not Experienced by Plaintiff

Defendants claim that the Court should exclude as irrelevant any and all "complications that Mrs. Wiltgen has not sustained or that no expert physician has reliably opined that she likely will sustain in the future." (R. 176 at 7-8.) Defendants argue that "expert testimony must fit the facts of the case and have a valid scientific connection to the pertinent inquiry." (*Id*. at 8 (quotations omitted).) "Evidence of complications that the plaintiff did not experience is irrelevant and lacking in probative value." (*Id.* (quoting *In re: Ethicon, Inc. v. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500767, *5 (S.D. W.Va. Aug. 26, 2016).) Further, Defendants argue, this evidence would be "highly misleading and confusing, as well as unduly prejudicial." (*Id*.)

Plaintiffs argue that the general complications of the TVT device, whether or not personally suffered by Plaintiff Mrs. Wiltgen, are relevant to the risk-utility test and to Plaintiff's failure-to-warn claim under Illinois law. (R. 189 at 12-14.) "The risk-utility analysis requires the jury to consider all known risks and complications of a device"—not just those suffered by Plaintiff. (*Id*. at 13.) Similarly, Plaintiffs argue, for the jury "to determine whether the warnings were accurate and sufficient." (*Id*.) Plaintiffs point out that Defendants raise the learned intermediary doctrine as a defense. (*Id*. at 14.) Under Illinois law, doctors who receive

inadequate warnings are not considered learned intermediaries, and evidence of all possible risks and complications is necessary for the jury to assess this defense. (*Id*.)

The Court agrees with Plaintiffs that Dr. Elliott's testimony on risks and complications not experienced by Plaintiff Mrs. Wiltgen is both relevant and admissible. Under Illinois product liability law, whether a product is unreasonably dangerous is evaluated under a test that involves "a broad range of factors," including "the magnitude and probability of the foreseeable risk of harm" *Mikolajczyk*, 901 N.E.2d at 352 (Ill. 2008). The jury must have all information before it to perform that balancing analysis. If all of the benefits of the product are admitted (even ones beyond those experienced by Plaintiff Mrs. Wiltgen), it only makes sense for all of the risks to be admitted as well. In *Herrera-Nevarez*, Judge Kennelly allowed other complications to come in to evidence on these grounds. 2017 WL 3381718 at *6-8.

With regard to Plaintiffs' failure to warn argument, the jury must know the full range of risks and complications to be able to compare and assess the sufficiency of the product's warnings. Plaintiffs are also correct that under Illinois law, doctors who receive insufficient warnings are not considered learned intermediaries. *See, e.g.*, *Hansen v. Baxter Healthcare Corp*., 764 N.E.2d 35, 43 (Ill. 2002) ("Doctors who have not been sufficiently warned of the harmful effects of a drug cannot be considered learned intermediaries and the adequacy of warnings is a question of fact, not law, for the jury to determine.") (quotations and emphasis omitted) (citing *Proctor v. Davis*, 682 N.E.2d 1203 (Ill. 1997)). If Defendants raise the learned intermediary doctrine at trial, Plaintiffs may rebut this defense.

Plaintiff Mrs. Wiltgen must establish that the design defect caused her particular injuries, but the gamut of possible injuries is admissible for both the risk-utility test and the failure-to-warn claim. The Court denies Defendants' motion with regard to Dr. Elliott's testimony on risks

and complications not experienced by Plaintiff Mrs. Wiltgen. Plaintiffs can offer evidence about the overall risks and benefits of the product to prove that a design defect existed and that the product's warnings were inadequate.

VI. Testimony Regarding Product Warnings

As a preliminary matter, Defendants admit that they failed to raise this argument before Judge Goodwin with the MDL Court. (R. 176 at 8-9.) The Court appreciates the candor and also appreciates Defendants' reasons for why they did not previously make this argument. Judge Goodwin had ruled that another urogynecologist could opine on the adequacy of the product's warnings, and it seemed both futile and a waste of resources to raise this issue before the MDL Court. Additionally, the Judge later changed his ruling in subsequent cases. *See, e.g., In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4536885, *2 (S.D. W.Va. Aug. 30, 2016) (excluding Dr. Margolis's warning opinions); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 2016 WL 4500767, *4 (S.D. W.Va. Aug. 26, 2016) (excluding Dr. Blaivas's warning opinions). Given Defendants' good faith reason, the Court will entertain this argument.

Defendants seek to exclude Dr. Elliott's testimony regarding the TVT's IFU. (R. 176 at 8-10.) The MDL Court held that: "While an expert who is a[n] urogynecologist may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU." *In re: Ethicon, Inc*., 2016 WL 4536885, *2 (S.D. W.Va. Aug. 30, 2016). Defendants dispute that Dr. Elliott has any of the requisite "additional expertise" that the MDL Court requires for him to opine on the adequacy of Ethicon's IFU.

Plaintiffs counter that the Court should permit Dr. Elliott to testify about the TVT's product warnings. (R. 189 at 14-15.) Plaintiffs claim that Dr. Elliott will not discuss warnings in a regulatory sense but will only discuss particular risks of the TVT and explain that the IFU failed to disclose those risks. (*Id*. at 15.) Plaintiffs cite *Hovey v. Cook Inc*. for the premise that the MDL Court has already denied Defendants' objections to Dr. Elliott's testimony on this subject. 2015 WL 1405565 (S.D. W.Va. Mar. 26, 2015). In that case, Judge Goodwin denied the motion to exclude Dr. Elliott's testimony about product warnings and labeling: "Relying on the plaintiff's assurance that Dr. Elliott's testimony will be limited to an evaluation of Cook's warnings based on his knowledge of and clinical experience with the risks of SIS products—and not on FDA requirements or regulations." *Id*. at *10.

The Court agrees with Plaintiffs, but limits Dr. Elliott's testimony to an evaluation of the TVT's IFU "based on his knowledge of and clinical experience with the risks" of SUI products "and not on FDA [or other] requirements or regulations." *Hovey*, 2015 WL 1405565 at *10. He may testify regarding the IFU from a physician's viewpoint, not from a regulatory basis. The additional expertise that Defendants claim is necessary for an expert to opine on "what information should or should not be included in an IFU" is only required of the urogynecologist who holds himself or herself out to be "an expert in the development of warning labels" and wishes to give related testimony. *In re: Ethicon, Inc*., 2016 WL 4536885 at *2. The Court thus grants in part and denies in part Defendants' motion. Dr. Elliott may give testimony on the TVT's IFU, but the testimony must be limited to his area of expertise, and his opinions must not involve legal or regulatory matters.

CONCLUSION

For the foregoing reasons, the Court grants in part and denies in part Defendants' *Daubert* motion challenging Dr. Elliott's testimony. The motion is granted with regard to Dr. Elliott's testimony about the legal or regulatory adequacy of Ethicon's research and testing, and Ethicon's product warnings. The motion is denied with regard to Dr. Elliott's testimony about non-synthetic mesh procedures and other synthetic mesh devices as safer alternatives to the TVT, the impact Ethicon's research and testing had on his opinions here, his testimony about other risks and complications of the TVT, and his opinion as a clinician about Ethicon's product warnings.

DATED: October 6, 2017

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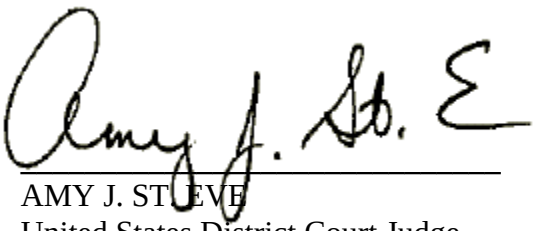

AMY J. STEVE
United States District Court Judge